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Remarks

This Amendment is responsive to the Official Action mailed October 22, 2002 (Paper No. 6). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully request.

Claims

Claims 60-67 were pending. Claims 60-67 stand rejected.

It is believed that entry of this Amendment is timely filed. Notwithstanding, Applicants hereby authorize the Commissioner to charge any additional claim fees required by entry of this Amendment to Deposit Account No. 05-0258.

Claims 60, 61 and 67 have been amended to more clearly recite the present invention. Support for this amendment is apparent. Thus, no new matter is added.

The Abstract

The Examiner noted that an Abstract of the Disclosure was missing. Applicant submits herewith a copy of the Abstract submitted in priority application PCT/EP99/03822.

Rejections under 35 U.S.C. §112(2)

Claim 60 was rejected under 35 U.S.C. §112, second paragraph for indefiniteness in recitation of the term, "matching." Claim 60 has been amended to no longer recite the term, "matching." Withdrawal of rejection is respectfully requested.

Claim 61 was rejected for depending on itself. Claim 61 has been amended to depend on claim 60. Withdrawal of rejection is respectfully requested.

Claim 67 was rejected under 35 U.S.C. §112, second paragraph for lack of antecedent basis in recitation of the term, "vaccine." Claim 67 has been amended to correct this clear typographical error and to recite proper antecedent basis. Amendment to claim 67 is meant solely to correct a typographical error and is not meant to exclude vaccines as a member of the more general class of immunogenic compositions. Withdrawal of rejection is respectfully requested.

Claim Rejections under 35 U.S.C. §102(e)

Claims 60-67 were rejected under 35 U.S.C. §102(e) as being anticipated by Peak et al. (U.S. Patent 6,197,312). In particular, the Examiner alleged that

Peak et al disclose an isolated polypeptide SEQ ID NO:9 comprising an amino acid sequence that contains 594 amino acids and matches with SEQ ID NO:2 in column 55-57 and claims U.S. Patent 6,197,312 (also see the attached sequence alignment also). Further, the prior art also discloses immunogenic fragments containing at least 50 amino acids that include 15-20 amino acids of the claimed invention (see claim 5), fusion proteins (see figure 1 and examples 2-4) and immunogenic compositions (see claims 7-10). The prior art anticipated the claimed invention.

Applicants traverse this rejection. First, with respect to SEQ ID NO:2, Peak et al is not a valid prior art reference under 35 U.S.C. §102(e) for amended claims 60-67. The earliest date that Peak et al was publicly available as a reference was well after Applicants' May 13, 1998 priority date in the instant application. As set forth in the Examination Guidelines for 35 U.S.C. §102(e), as amended by the American Inventors Protection Act of 1999, and further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, if a U.S. patent resulted from an international application filed before November 29, 2000, the U.S. patent will have a prior art date per §102(e) in effect prior to November 29, 2000. Further, a U.S. or WIPO publication of an international application filed prior to November 29, 2000 will have no prior art effect under §102(e). Applicants enclose herewith a copy of relevant portions of the Examination Guidelines as published on the US PTO website. Withdrawal of rejection is respectfully requested.

With respect to SEQ ID NO:4, Applicants assert that Peak et al. does not disclose, either inherently or explicitly a polypeptide comprising the amino acid sequence of SEQ ID NO:4 of the instant invention. Withdrawal of rejection is respectfully requested.

Serial No.: 09/700,293
Group Art Unit: 1645

FEE DEFICIENCY

☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time. The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 50-0258.

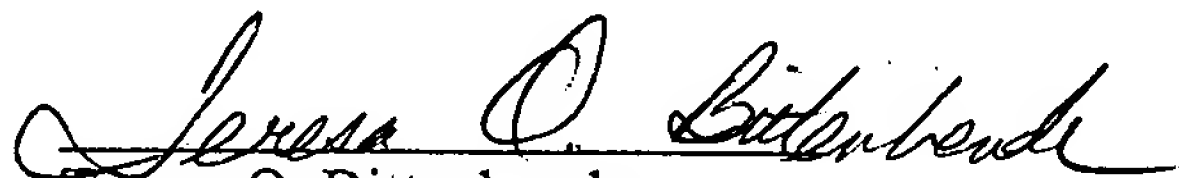
and/or

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Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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January 21, 2003

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Detail of claim amendments

60. (Amended) An isolated polypeptide comprising a member selected from the group consisting of

- (a) the[an] amino acid sequence of[matching] SEQ ID NO:2 or SEQ ID NO:4;
- (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2 or SEQ ID NO:4;

wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell immune response to a polypeptide having the sequence of SEQ ID NO:2 or SEQ ID NO:4[;].

61. (Amended) The isolated polypeptide of claim 60[61], wherein the polypeptide is according to (a).

67. (Amended) The immunogenic composition of Claim 66, wherein the immunogenic composition further[vaccine] comprises at least one other *Neisseria Meningitidis*[*Moraxella catarrhalis*] antigen.

Claims following entry of amendment mailed January 21, 2003

60. (Amended) An isolated polypeptide comprising a member selected from the group consisting of

- (a) the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4;
- (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2 or SEQ ID NO:4;

wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell immune response to a polypeptide having the sequence of SEQ ID NO:2 or SEQ ID NO:4.

61. (Amended) The isolated polypeptide of claim 60, wherein the polypeptide is according to (a).

62. The isolated polypeptide of claim 60, wherein the polypeptide is according to (b).

63. The isolated polypeptide of claim 60, wherein the immunogenic fragment of (b) comprises at least 20 amino acids.

64. The isolated polypeptide of claim 60, wherein the isolated polypeptide consists of SEQ ID NO:2 or SEQ ID NO:4.

65. A fusion protein comprising the isolated polypeptide of Claim 60.

66. An immunogenic composition comprising the polypeptide of Claim 60 and a pharmaceutically acceptable carrier.

67. (Amended) The immunogenic composition of Claim 66, wherein the immunogenic composition further comprises at least one other *Neisseria Meningitidis* antigen.

Examination Guidelines for 35 U.S.C. § 102(e), as amended by the American Inventors Protection Act of 1999, and further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, and 35 U.S.C. § 102(g) (Revised ¹)

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This notice sets forth the interpretation by the United States Patent and Trademark Office (USPTO or Office) of 35 U.S.C. §§ 102(e) and 374, as amended by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)), and as further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215) (Pub. L. 107-273 (2002)). This notice also clarifies the Office's policy on prior art rejections based on 35 U.S.C. § 102(g).

Generally, 35 U.S.C. § 102(e), after enactment of the AIPA and H.R. 2215, is similar to the pre-AIPA § 102(e), with two significant differences, which may be summarized as: (1) in addition to U.S. patents, now certain **publications** of U.S. and international applications may be applied as of their filing dates in a prior art rejection; and (2) certain **international filing dates** are now U.S. filing dates for prior art purposes under § 102(e), and U.S. patents and certain application publications may now be applied as of these international filing dates in a prior art rejection.

Specifically, this notice provides guidance that prior art, as defined by § 102(e) of the patent code in effect on November 29, 2000, includes U.S. patents, publications of U.S. patent applications and World Intellectual Property Organization's (WIPO) publications of international applications, provided such references do not directly or indirectly result from an international application filed before November 29, 2000. **If a U.S. patent resulted from an international application filed before November 29, 2000, the U.S. patent will have a prior art date per § 102(e) in effect prior to November 29, 2000, which is the earlier of the date of compliance with § 371(c)(1), (2) and (4) of the patent code (e.g. National Stage entry) or the filing date of the later-filed U.S. application that claimed the benefit of the international application. A U.S. or WIPO publication of an international application filed prior to November 29, 2000 will have no prior art effect under § 102(e). Such publications do, however, have prior art effect under § 102(a) or (b) as of their publication dates.**

Furthermore, all pending U.S. patent applications being examined, and all U.S. patents being reexamined, or otherwise being contested, whenever filed, are subject to the amended version of § 102(e).

This notice also provides examples of the determination of § 102(e) dates for references based on the most common factual scenarios. The examples that best highlight the recent change to §§ 102(e) and 374 are the examples that involve a WIPO publication of an international application under PCT Article 21(2), a U.S. publication of an international application, or a U.S. patent derived from an international application.

The policy and practice set forth in the Official Gazette Notice entitled "Examination Guidelines for 35 U.S.C. § 102(e)(2), as amended by the American Inventors Protection Act of 1999," 1243 O.G. 1037 (Feb. 27, 2001) and guidelines provided in the Manual of

Patent Examining Procedure (MPEP) concerning the changes made by the AIPA to 35 U.S.C. § 102(e) (e.g., MPEP 706.02(a), Part II; 901.03; 1895.01, Part E; 1896; and 2136 et seq., Eighth Edition (August 2001)) are superceded by this notice and should no longer be followed.

SIGNIFICANT PROVISIONS:

A. Effective Date Provisions of the Amendments.

The technical correction legislation in H.R. 2215 provides for the application of revised 35 U.S.C. § 102(e) in the examination of all applications, whenever filed, and the reexamination of, or other proceedings to contest, all patents. The filing date of the application is no longer relevant in determining what version of § 102(e) to apply in determining the patentability of that application, or the patent resulting from that application. The revised statutory provisions supercede all previous versions of §§ 102(e) and 374, with only one exception, which is when the potential reference is based on an international application filed prior to November 29, 2000 (discussed further in section D below). Furthermore, the provisions amending §§ 102(e) and 374 in H.R. 2215 are completely retroactive to the effective date of the relevant provisions in the AIPA (November 29, 2000).

B. U.S. and WIPO application publications may have a § 102(e)(1) prior art date.

Paragraph (e) of 35 U.S.C. § 102 was amended by the AIPA to create two separate clauses, namely, § 102(e)(1) for **publications** of patent applications and § 102(e)(2) for patents. Section 102(e)(1), in combination with amended § 374, created a new category of prior art by providing prior art effect for certain **publications** of patent applications, including international applications, as of their effective United States filing dates (which will include certain international filing dates). Under H.R. 2215's revised § 102(e), an international filing date, which is on or after November 29, 2000, is a United States filing date for prior art purposes under 35 U.S.C. § 102(e) if the international application designated the United States and was published by the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty (PCT) Article 21(2) in the English language. Publication under PCT Article 21(2) may result from a request for early publication by an international applicant or after the expiration of 18-months after the earliest claimed filing date in an international application. An applicant that has designated only the U.S. would continue to be required to request publication from WIPO as the reservation under PCT Article 64(4) continues to be in effect for such applicants.

C. A patent from an international application may have a § 102(e)(2) prior art date of its international filing date.

Paragraph (e) of 35 U.S.C. § 102 was also amended by the AIPA to eliminate the reference to fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements. As a result, United States **patents** issued directly from international applications filed on or after November 29, 2000 will no longer be available as prior art under § 102(e) as of the date the requirements of § 371 (c)(1), (2) and (4) have been satisfied. Under § 102(e)(2), as amended by the AIPA and H.R. 2215, an international filing date, which is on or after November 29, 2000, is a United States filing date for purposes of determining the earliest

effective prior art date of a patent if the international application designated the United States and was published in the English language under PCT Article 21(2) by WIPO.

D. International filing dates prior to November 29, 2000 cannot be used under § 102(e) for prior art purposes.

No international filing dates prior to November 29, 2000 may be relied upon as a prior art date under § 102(e) in accordance with the last sentence of the effective date provisions (reproduced below in section I). **Patents** issued directly, or indirectly, from international applications filed before November 29, 2000 may only be used as prior art based on the provisions of § 102(e) in effect before November 29, 2000. Thus, the date of such a prior art patent is the earliest of the date of compliance with 35 U.S.C. § 371(c)(1), (2) and (4), or the filing date of the later-filed U.S. continuing application that claimed the benefit of the international application. **Publications** of international applications filed before November 29, 2000 (which would include WIPO publications and U.S. publications of the National Stage (§ 371)) do not have a § 102(e) date at all. Specifically, under § 374, the international application must be filed on or after November 29, 2000 for its WIPO publication to be “deemed a publication under section 122(b)” and thus available as a possible prior art reference under § 102(e) as amended by the AIPA.

E. Additional requirements for international applications filed on or after November 29, 2000.

If an international application was filed on or after November 29, 2000, the international application must have **designated the U.S.** and been **published in English** under PCT Article 21(2) by WIPO in order for its international filing date to be a U.S. filing date for purposes of § 102(e) and be relied upon as a prior art date.

F. When an international application cannot serve as a bridge to an earlier-filed application.

International applications, which: (1) were filed prior to November 29, 2000, (2) did not designate the U.S., or (3) were not published in English under PCT Article 21(2) by WIPO, may not be used to reach back (bridge) to an earlier filing date through a priority or benefit claim for prior art purposes under 35 U.S.C. § 102(e).

DISCUSSION: Sections I – V below set forth the USPTO’s examination procedures for the amendments to 35 U.S.C. § 102(e) made by the AIPA and H.R. 2215.

I) Statutory Language of 35 U.S.C. §§ 102(e) and 374:

Pre-AIPA § 102(e): Now, only applies to Patents derived from International Applications filed before November 29, 2000:

“A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by applicant for patent, or”.

Revised § 102(e): For examining all Applications, whenever filed, and for reexamining of all Patents, and for determining the prior art dates² of Patents and certain Application Publications:

A person shall be entitled to a patent unless
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

Pre-AIPA § 374: For WIPO Publications of International Applications filed prior to November 29, 2000:

The publication under the treaty of an international application shall confer no rights and shall have no effect under this title other than that of a printed publication.

Revised § 374: For WIPO Publications of International Applications filed on or after November 29, 2000:

The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall be deemed a publication under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

Effective Date Provisions for the amendments to §§ 102(e) and 374³, as amended by H.R. 2215:

Except as otherwise provided in this section, sections 4502 through 4504 and 4506 through 4507, and the amendments made by such sections, shall be effective as of November 29, 2000, and shall apply only to applications (including international applications designating the United States) filed on or after that date. The amendments made by section 4504 shall additionally apply to any pending application filed before November 29, 2000, if such pending application is published pursuant to a request of the applicant under such procedures as may be established by the Director.

Except as otherwise provided in this section, the amendments made by section 4505 shall be effective as of November 29, 2000 and shall apply to all patents and all applications for patents pending on or filed after November 29, 2000. Patents resulting from an international application filed before November 29, 2000 and applications published pursuant to section 122(b) or Article 21(2) of the treaty defined in section 351(a) resulting from an international application filed before November 29, 2000 shall not be effective as prior art as of the filing date of the international application; however, such patents shall be effective as prior art in accordance with section 102(e) in effect on November 28, 2000.

II) Impact of Statutory Changes and Effective Date of the Changes

As shown above, 35 U.S.C. § 102(e) has been amended to have two separate clauses, namely, (e)(1) for **publications** of patent applications, and (e)(2) for **patents**.

With respect to revised 35 U.S.C. § 102(e)(1) and 35 U.S.C. § 374, a new category of prior art is created for **publications** of patent applications. This new category includes the following two types of published patent applications:

- (1) U.S. publications of patent applications filed in the United States by another which are published under § 122(b) of title 35, United States Code; and
- (2) U.S. and WIPO publications of international applications, filed on or after November 29, 2000, by another that designated the United States and were published in the English language under PCT Article 21(2) by WIPO.

In summary, under amended §§ 102(e)(1) and 374, certain **publications** of patent applications, including certain WIPO publications of international applications (under PCT Article 21(2)) which are filed on or after November 29, 2000, are considered to be prior art as of their earliest effective United States filing date. It is important to note that a U.S. application publication of a National Stage of an international application or a WIPO publication of an **international application** under §§ 102(e)(1) and 374, as amended by H.R. 2215, can be prior art as of the international filing date if the international application had an international **filing date on or after November 29, 2000, designated the United States, and was published in English** under PCT Article 21(2) by WIPO. Prior to the AIPA amendments to §§ 102(e) and 374, a WIPO publication of an international application could only be prior art under § 102(a) or (b) as of the publication date (and there were no U.S. application publications).

Paragraph (e) of 35 U.S.C. § 102 was also amended to modify what U.S. **patents** are available as prior art under this subsection. Section 102(e)(2) no longer recognizes the date of fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements for prior art purposes. Section § 102(e)(2), however, considers an international filing date that is on or after November 29, 2000 as a United States filing date for purposes of determining the earliest effective prior art date of a patent if the international application designated the United States and was published in the English language under PCT Article 21(2) by WIPO.

The AIPA and H.R. 2215 also establish when the amendments to §§ 102(e) and 374 must be applied. First, the AIPA and H.R. 2215 set forth that the amendments to § 102(e) apply to all applications being examined and all patents under reexamination. See the third sentence of § 4508 of the AIPA, as amended by H.R. 2215 (addressing § 4505 of the AIPA). In other words, the revised version of § 102(e) is completely retroactive, and it applies to all applications, no matter when filed, and all patents, with only one exception, which pertains to applying, as prior art under § 102(e), patents or publications based on international applications filed prior to November 29, 2000. Further, the amendments to § 374, which "deems" certain WIPO publications of international applications under PCT Article 21(2) as U.S. publications of applications filed under 35 U.S.C. § 111(a), are only effective for international applications filed on or after November 29, 2000. Therefore, an international application must be filed on or after November 29, 2000 for its WIPO publication to be "deemed a publication under section 122(b)," and thus available as a possible prior art reference under § 102(e)(1).

III) Prior Art Rejections based on 35 U.S.C. § 102(g)

35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence, while more commonly applied to interference matters, also arise in other contexts.

35 U.S.C. § 102(g) may form the basis for an *ex parte* rejection if: (1) the subject matter at issue has been actually reduced to practice by another before the applicant's invention, and (2) there has been no abandonment, suppression or concealment. See, e.g., *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1205, 18 USPQ2d 1016, 1020 (Fed. Cir. 1991); *New Idea Farm Equipment Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434, 7 USPQ2d 1129, 1132 (Fed. Cir. 1988); *Kimberly Clark v. Johnson & Johnson*, 745 F.2d 1437, 1444-46, 223 USPQ 603, 606-08 (Fed. Cir. 1984). To qualify as prior art under 35 U.S.C. § 102(g), however, there must be evidence that the subject matter was actually reduced to practice, in that conception alone is not sufficient. See *Kimberly Clark*, 745 F.2d at 1445, 223 USPQ at 607. While the filing of an application for patent is a constructive reduction to practice, the filing of an application does not in itself provide the evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. § 102(g). Thus, absent evidence showing an actual reduction to practice (which is generally not available during *ex parte* examination), the disclosure of a United States patent application publication or patent falls under 35 U.S.C. § 102(e) and not under 35 U.S.C. § 102(g). Cf. *In re Zletz*, 893 F.2d 319, 323, 13 USPQ2d 1320, 1323 (Fed. Cir. 1990) (the disclosure in a reference United States patent does not fall under 35 U.S.C. § 102(g) but under 35 U.S.C. § 102(e)).

In addition, subject matter qualifying as prior art only under 35 U.S.C. § 102(g) may also be the basis for an *ex parte* rejection under 35 U.S.C. 103. See *In re Bass*, 474 F.2d 1276, 1283, 177 USPQ 178, 183 (CCPA 1973) (in an unsuccessful attempt to utilize a 37 CFR

1.131 affidavit relating to a combination application, applicants admitted that the subcombination screen of a copending application which issued as a patent was earlier conceived than the combination). 35 U.S.C. § 103(c), however, states that subsection (g) of 35 U.S.C. § 102 will not preclude patentability where subject matter developed by another person, that would otherwise qualify under 35 U.S.C. § 102(g), and the claimed invention of an application under examination were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made. See MPEP §§ 706.02(l) and 2146 (Eighth Edition (Aug. 2001)).

For additional examples of 35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence outside the context of interference matters, see *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983) (discussing the concepts of conception and constructive reduction to practice in the context of a declaration under 37 CFR 1.131), and *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973) (holding constructive reduction to practice for priority under 35 U.S.C. § 119 requires meeting the requirements of 35 U.S.C. §§ 101 and 112).

IV) Examination Procedures under 35 U.S.C. §§ 102(e) and 374

- (1) Determine the effective filing date(s) of the application being examined.
See the Manual of Patent Examining Procedure (MPEP), sections 706.02, 1893.03(b), 1893.03(c), 1895 and 1895.01, Eighth Edition (Aug. 2001) as revised by this notice.
- (2) Determine and perform an appropriate prior art search.
The Examiner should search for the most relevant prior art under 35 U.S.C. §§ 102 and 103, including U.S. and WIPO **publications** of patent applications, and U.S. **patents** accorded prior art dates under § 102(e).
- (3) Determine if the potential reference under § 102(e) is "by another."
The inventive entity of the application must be different than that of the reference in order to apply a reference under § 102(e). Note that, where there are joint inventors, only one inventor need be different for the inventive entities to be different and a rejection under § 102(e) may be applicable even if there are some common inventors. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.
- (4) Determine the appropriate § 102(e) date for each potential reference by following the guidelines below and examples set forth under Part V:
 - (a) The potential reference must be a U.S. patent, a U.S. application publication (35 U.S.C. § 122(b)) or a WIPO publication of an international application under PCT Article 21(2) in order to apply the reference under § 102(e).
 - (b) Determine if the potential reference resulted from, or claimed the benefit of, an international application. If the reference does, go to step (c) below.

The § 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper priority or benefit claims to prior U.S. applications under §§ 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.

- (c) If the potential reference resulted from, or claimed the benefit of, an international application, the following must be determined:
 - i. If the international application meets the following three conditions:
 - 1. an international filing date on or after November 29, 2000;
 - 2. designated the United States; and
 - 3. published under PCT Article 21(2) in English,
 the international filing date is a U.S. filing date for prior art purposes under § 102(e). If such an international application properly claims benefit to an earlier-filed U.S. or international application, or priority to an earlier-filed U.S. provisional application, apply the reference under § 102(e) as of the earlier filing date, assuming all the conditions of §§ 102(e), 119(e), 120, or 365(c) are met. Note, where the earlier application is an international application, the earlier international application must satisfy the same three conditions (i.e., filed on or after November 29, 2000, designated the U.S. and had been published in English under PCT Article 21(2)).
 - ii. If the international application was filed on or after November 29, 2000, but did **not** designate the United States or was **not** published in English under PCT Article 21(2), do **not** treat the international filing date as a U.S. filing date for use under 35 U.S.C. § 102(e) as a prior art date. In this situation, do **not** apply the reference as of its international filing date, its date of completion of the § 371(c)(1), (2) and (4) requirements, or any earlier filing date to which such an international application claims benefit or priority. The reference may be applied under § 102(a) or (b) as of its publication date, or § 102(e) as of any later U.S. filing date of an application that properly claimed the benefit of the international application (if applicable).
 - iii. If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of §§ 102 and 374, prior to the AIPA amendments:
 - 1. For U.S. patents, apply the reference under § 102(e) as of the earlier of the date of completion of the requirements of § 371(c)(1), (2) and (4) or the filing date of the later-filed U.S. application that claimed the benefit of the international application.

2. For U.S. application publications and WIPO publications of international applications under PCT Article 21(2), never apply these references under § 102(e). These references may be applied as of their publication dates under § 102(a) or (b).
3. For U.S. application publications of applications that claim the benefit of an international application filed prior to November 29, 2000, apply the reference under § 102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.
- iv. Examiners should be aware that although a publication of, or a U.S. Patent issued from, an international application may not have a § 102(e) date at all, or may have a § 102(e) date that is after the effective filing date of the application being examined (so it is not "prior art"), the corresponding WIPO publication of an international application will likely have an earlier § 102(a) or (b) date.
- (d) Foreign applications' filing dates that are claimed (via 35 U.S.C. §§ 119(a)-(d) or 365(a)) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may **not** be used as § 102(e) dates for prior art purposes. This would include international filing dates claimed as foreign priority dates under 35 U.S.C. § 365(a).

(5) Determine whether 35 U.S.C. § 103(c) common assignee considerations apply.

If a § 102(e) reference is applied in an obviousness rejection under 35 U.S.C. § 103(a) (including provisional rejections) in an application filed on or after November 29, 1999⁴, the examiner should ascertain whether there is evidence that the claimed invention and the reference were owned by the same person, or subject to an obligation of assignment to the same person, at the time the claimed invention was made. A clear statement of entitlement to the prior art exclusion by applicant(s) or a registered practitioner would be sufficient evidence to establish the prior art exclusion. A double patenting rejection, however, based on the § 102(e) reference could be applied, if appropriate, even if the reference is disqualified from being used a rejection under § 103(a). See MPEP 706.02(l), Eighth Edition (Aug. 2001).

(6) Apply the reference(s) under §§ 102 or 103, based on the provision of § 102 that gives the best prior art date for the disclosure. If a reference is prior art under both §§ 102 (a) and (e), but not § 102(b), the reference should be applied under both provisions.

- (a) Examiners should provide a copy of the appropriate statutory language under which the rejection is made in the first Office action utilizing such a rejection. Only revised (October 2002, or more current) Form Paragraphs pertaining to § 102(e) should be used.

(7) Final rejection practice: If a second or subsequent action contains a new ground of rejection necessitated by the change to 35 U.S.C. § 102(e) that was not also necessitated by an amendment to the claims or as a result of certain information disclosure statements, that action cannot be made final. See MPEP 706.07(a), Eighth Edition (Aug. 2001).

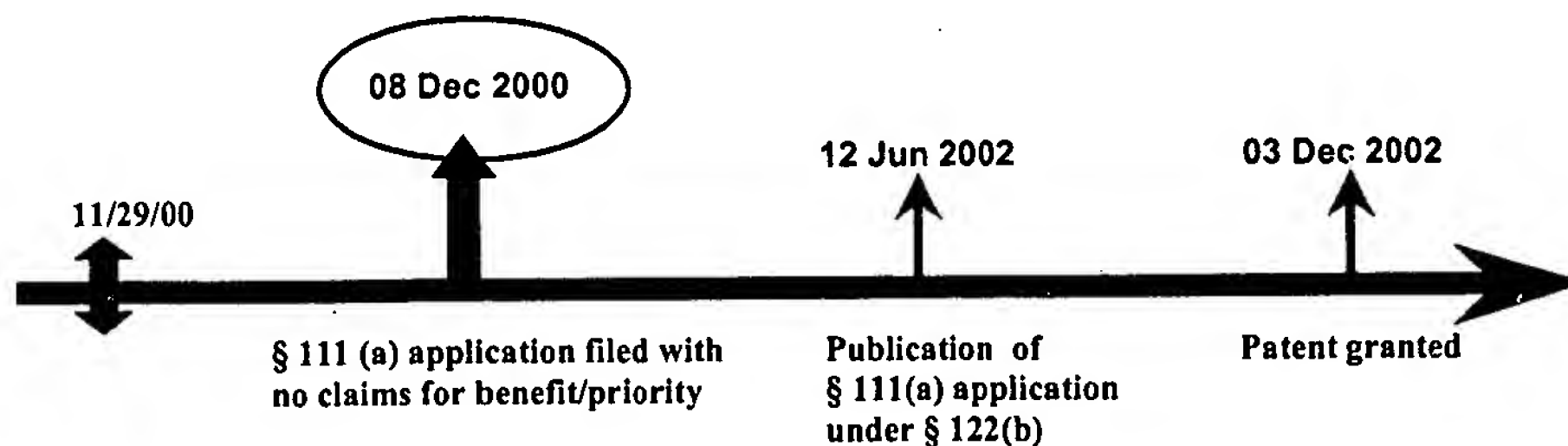
V) Examples

In order to illustrate the prior art dates of U.S. and WIPO **publications** of patent applications and United States **patents** under § 102(e), nine examples are presented below. The examples only cover the most common factual situations that might be encountered when determining the § 102(e) date of a reference. Examples 1 and 2 involve only U.S. application publications and U.S. patents. Example 3 involves a priority claim to a foreign patent application. Examples 4-9 involve international applications. The **time lines** in the examples below show the history of the prior art **references** that could be applied against the claims of the application under examination, or the patent under reexamination.

The dates in the examples below are arbitrarily used and are presented for illustrative purposes only. Therefore, correlation of patent grant dates with Tuesdays or application publication dates with Thursdays may not be portrayed in the examples.

Example 1: Reference Publication and Patent of § 111(a) Application with no Priority/Benefit Claims

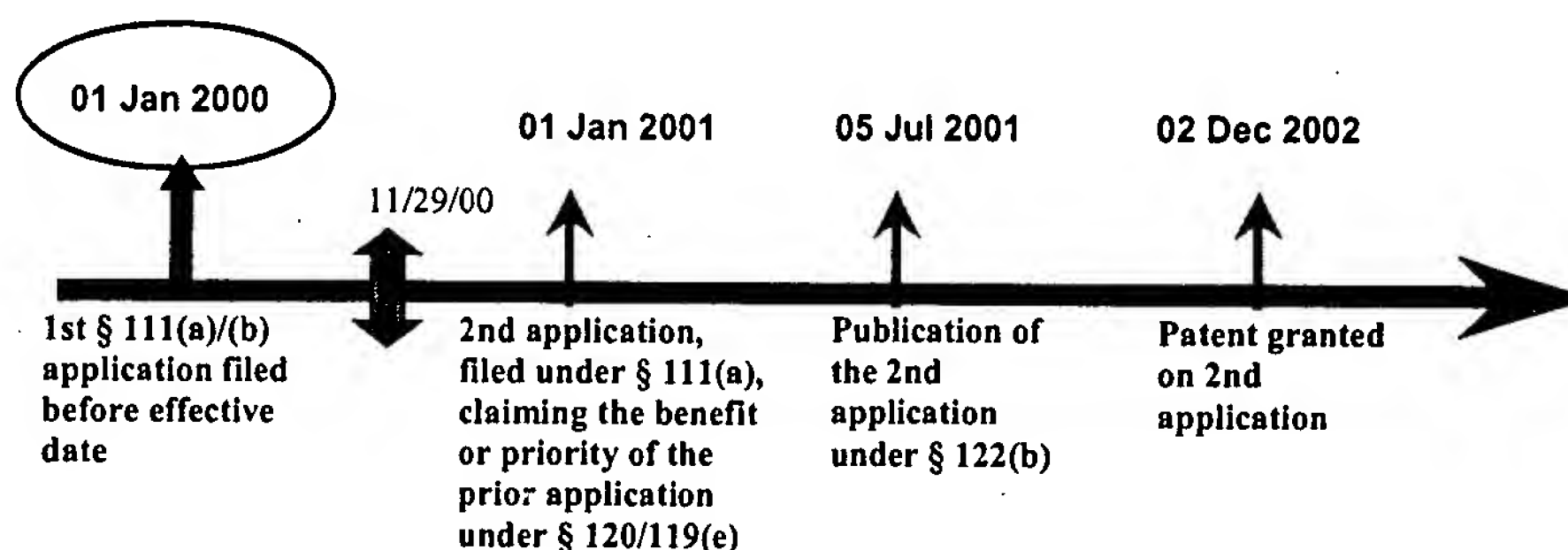
For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a) with no claim for the benefit of, or priority to, a prior application, the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing date. Thus, a publication and patent of a § 111(a) application, which does not claim any benefit under either 35 U.S.C. §§ 119(e), 120 or 365(c), would be accorded the application's actual filing date as its prior art date under § 102(e).



The § 102(e)(1) date for Publication is: 08 Dec 2000
 The § 102(e)(2) date for the Patent is: 08 Dec 2000

Example 2: Reference Publication and Patent of § 111(a) Application with Priority/Benefit Claim to a Prior U.S. Provisional or Nonprovisional Application

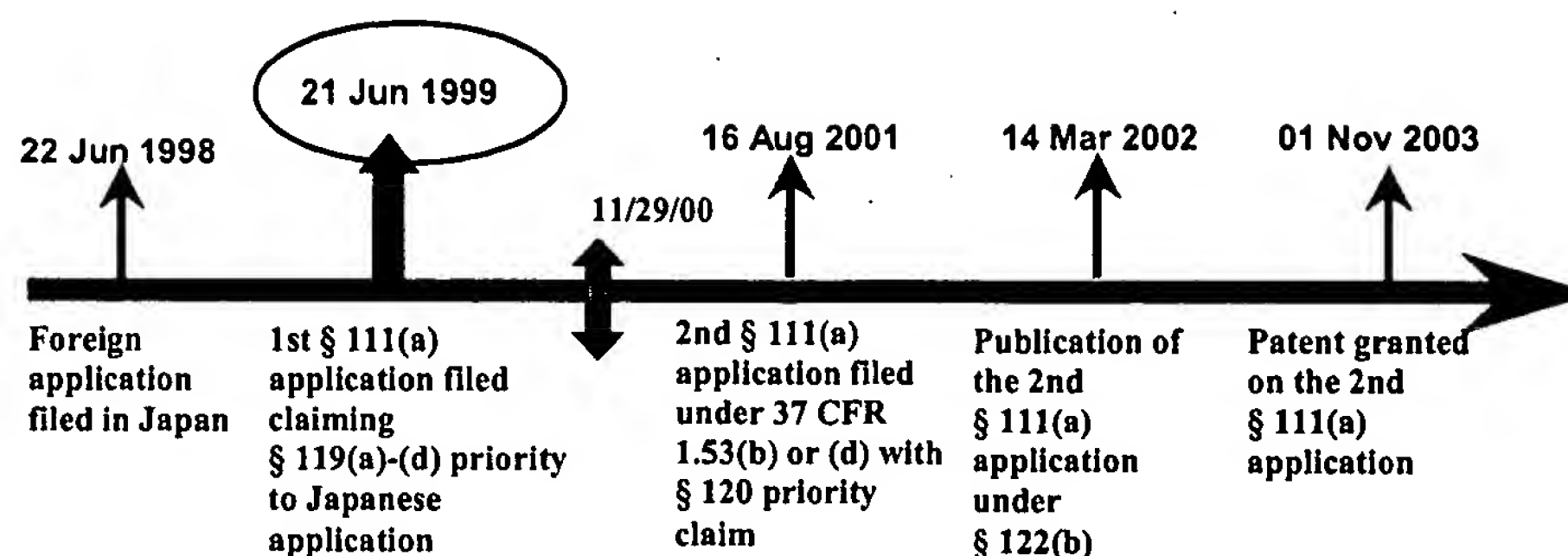
For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. Thus, a publication and patent of a § 111(a) application, which claims priority under 35 U.S.C. § 119(e) to a prior U.S. provisional application or claims the benefit under 35 U.S.C. § 120 of a prior nonprovisional application, would be accorded the earlier filing date as its prior art date under § 102(e), assuming the earlier-filed application has proper support for the subject matter as required by §§ 119(e) or 120.



The § 102(e)(1) date for Publication is: 01 Jan 2000
 The § 102(e)(2) date for the Patent is: 01 Jan 2000

Example 3: Reference Publication and Patent of § 111(a) Application with § 119(a)-(d) Benefit Claim to a Prior Foreign Application

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. No benefit of the filing date of the foreign application is given under § 102(e) for prior art purposes (*In re Hilmer*, 149 USPQ 480 (CCPA 1966)). Thus, a publication and patent of a § 111(a) application, which claims benefit under 35 U.S.C. § 119(a)-(d) to a prior foreign-filed application, would be accorded its United States filing date as its prior art date under § 102(e).

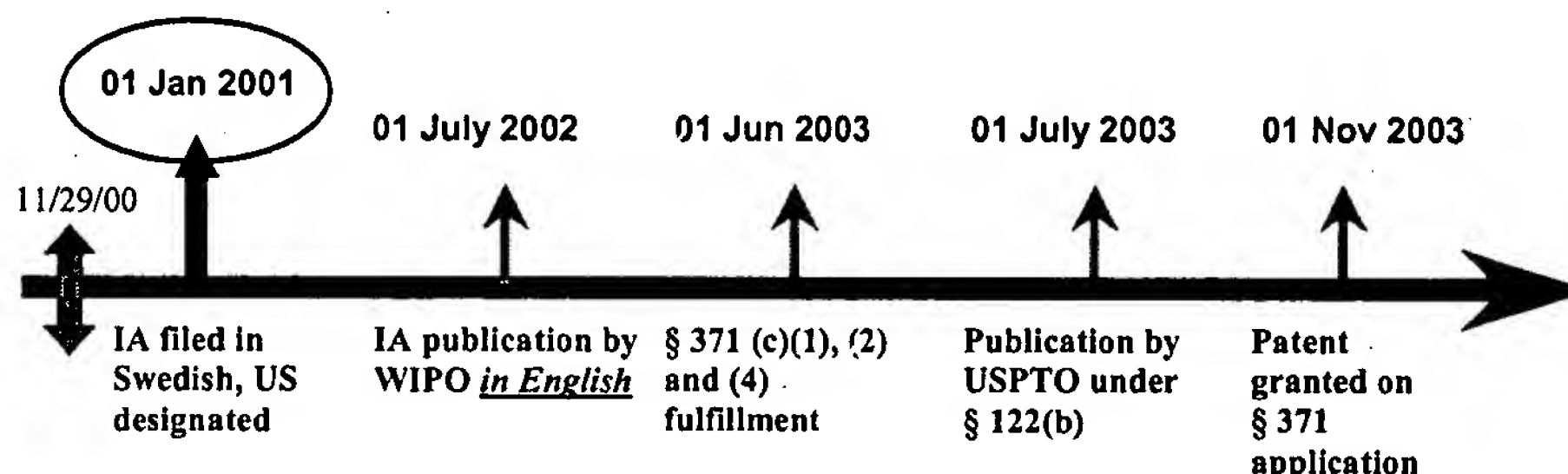


The § 102(e)(1) date for Publication is: 21 Jun 1999

The § 102(e)(2) date for the Patent is: 21 Jun 1999

Example 4: References based on the National Stage (§ 371) of an International Application filed on or after November 29, 2000 and which was published in English under PCT Article 21(2).

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that was filed on or after November 29, 2000, designated the U.S., and was published in English under PCT Article 21(2) by WIPO, have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English.



The § 102(e)(1) date for the IA publication by WIPO is: 01 Jan 2001

The § 102(e)(1) date for Publication by USPTO is: 01 Jan 2001

The § 102(e)(2) date for the Patent is: 01 Jan 2001

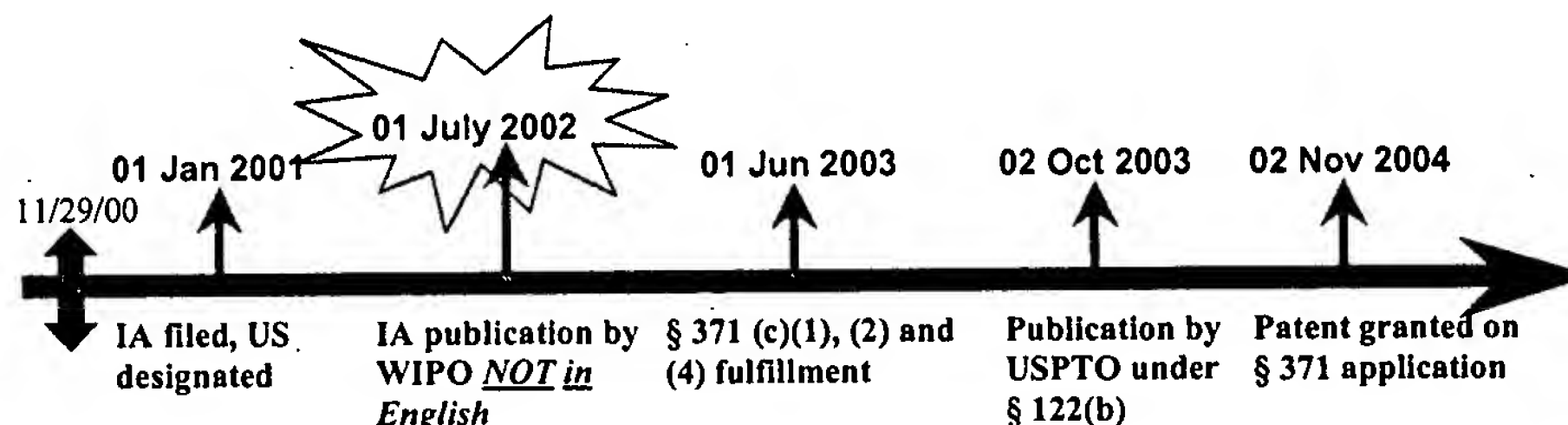
Additional Priority/Benefit Claims:

- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the international filing date, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120.

- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.

Example 5: References based on the National Stage (§ 371) of an International Application filed on or after November 29, 2000 and which was not published in English under PCT Article 21(2).

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that was filed on or after November 29, 2000 but was **not** published in **English** under PCT Article 21(2) by WIPO, have no § 102(e) prior art date at all. According to § 102(e), no benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English regardless of whether the international application entered the National Stage. Such references may be applied under § 102(a) or (b) as of their publication dates, but never under § 102(e).



The § 102(e)(1) date for the IA publication by WIPO is: None

The § 102(e)(1) date for Publication by USPTO is: None

The § 102(e)(2) date for the Patent is: None

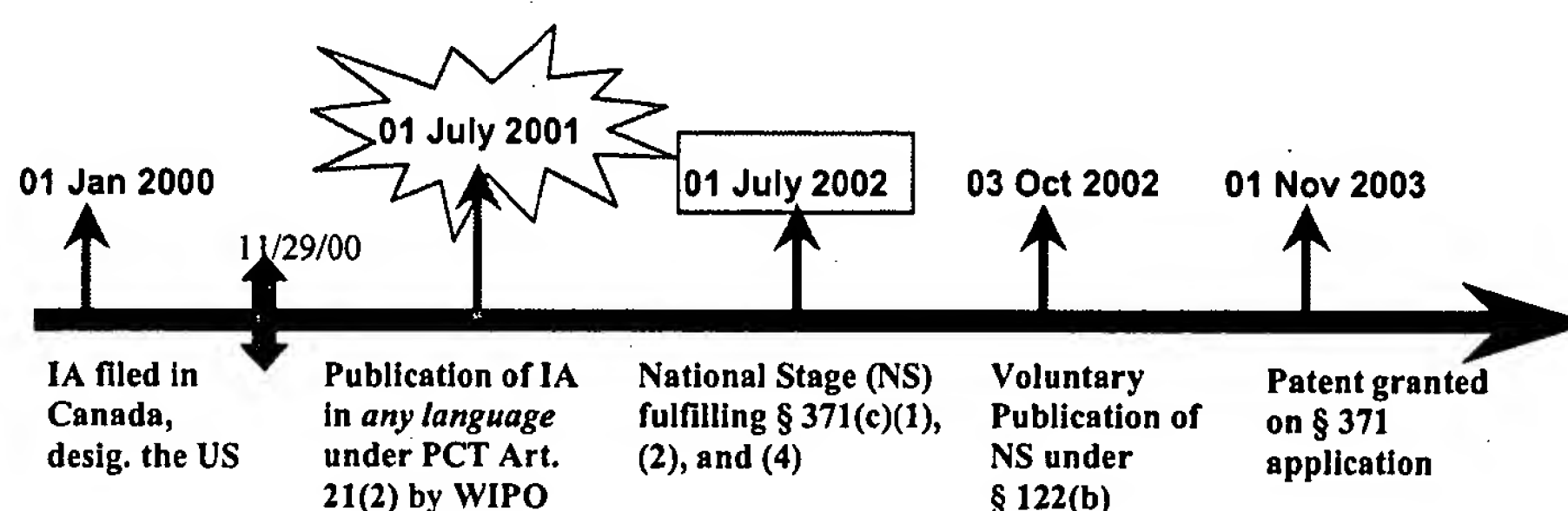
The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2002).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e) date for all the references.
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the actual filing date of the later-filed U.S. application.

Example 6: References based on the National Stage (§ 371) of an International Application filed prior to November 29, 2000 (language of the publication under PCT Article 21(2) is not relevant)

The reference U.S. patent issued from an international application (IA) that was filed prior to November 29, 2000 has a § 102(e) prior art date of the date of fulfillment of the requirements of 35 U.S.C. § 371(c)(1), (2) and (4). This is the pre-AIPA § 102(e). The application publications, both the WIPO publication and the U.S. publication, published from an international application that was filed prior to November 29, 2000, do not have any § 102(e) prior art date. According to the effective date provisions as amended by H.R. 2215, the amendments to §§ 102(e) and 374 are not applicable to international applications having international filing dates prior to November 29, 2000. The application publications can be applied under § 102(a) or (b) as of their publication dates.



The § 102(e)(1) date for the IA publication by WIPO is: None

The § 102(e)(1) date for Publication by USPTO is: None

The § 102(e) date for the Patent is: 01 July 2002

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2001).

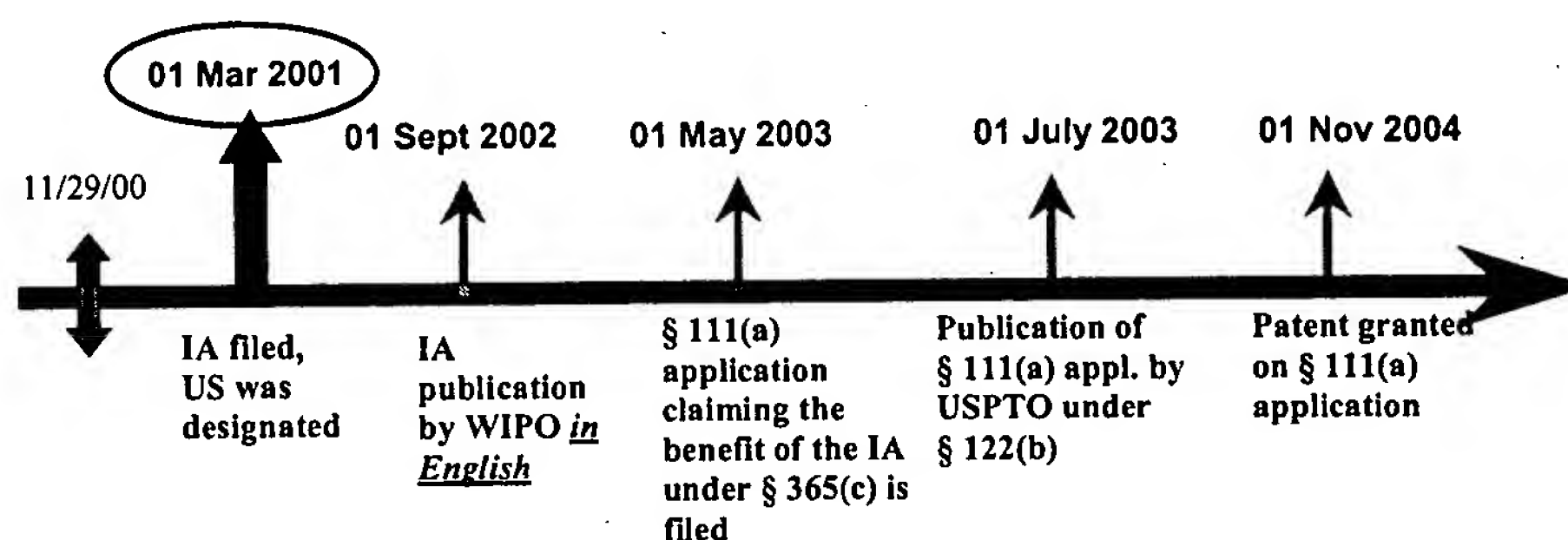
Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the U.S. and WIPO application publications, and the § 102(e) date for the patent will still be 01 July 2002 (the date of fulfillment of the requirements under § 371(c)(1), (2) and (4)).
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e)(1) date of the application publication of later-filed U.S. application would be the actual filing date of the later-filed U.S. application, and § 102(e) date of the patent of the later-filed U.S. application would be 01 July 2002 (the date that the earlier-filed IA fulfilled the requirements of § 371(c)(1), (2) and (4)).
- ✓ If the patent was based on a later-filed U.S. application that claimed the benefit of the international application and the later filed U.S. application's filing date is

before the date the requirements of 35 U.S.C. 371(c)(1)(2) and (4) were fulfilled (if fulfilled at all), the 102(e) date of the patent would be the filing date of the later-filed U.S. application that claimed the benefit of the international application.

Example 7: References based on a § 111(a) Application which is a **Continuation of an International Application**, which was filed on or after November 29, 2000, designated the U.S. and was published in English under PCT Article 21(2)

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent of, or claiming the benefit of, an international application (IA) that was filed on or after November 29, 2000, designated the U.S. and was published in English under PCT Article 21(2) by WIPO, have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) purposes if the IA was published under PCT Article 21(2) by WIPO in a language other than English.



The § 102(e)(1) date for the IA publication by WIPO is: 01 Mar 2001

The § 102(e)(1) date for Publication by USPTO is: 01 Mar 2001

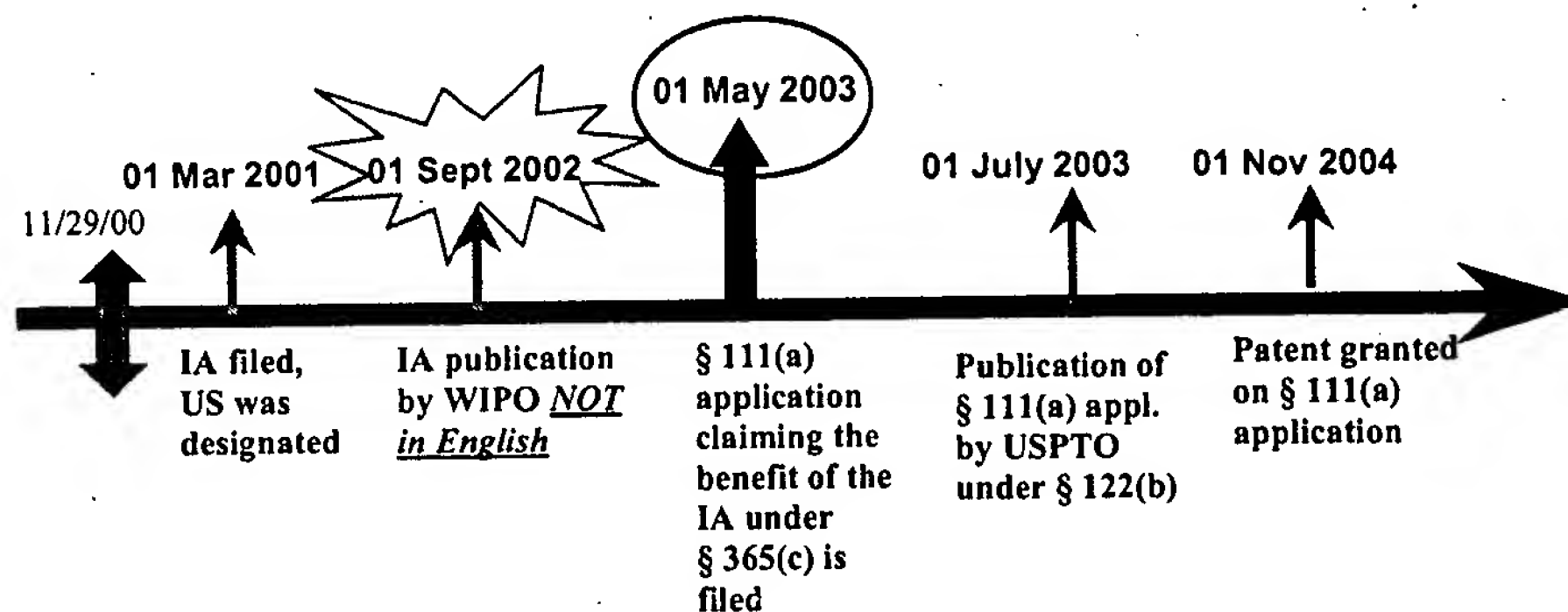
The § 102(e)(2) date for the Patent is: 01 Mar 2001

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.
 - ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the international filing date of the IA, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120 and 365(c).
-

Example 8: References based on a § 111(a) Application which is a
Continuation of an International Application, which was filed on or
 after November 29, 2000 and was **not published in English** under PCT
 Article 21(2)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation of an international application (IA) that was filed on or after November 29, 2000 but was **not** published in English under PCT Article 21(2) by WIPO have the § 102(e) prior art date of its actual U.S. filing date under § 111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) purposes if the IA was published under PCT Article 21(2) in a language other than English. The IA publication under PCT Article 21(2) does not have a prior art date under § 102(e)(1) because the IA was not published in English under PCT Article 21(2). The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.



The § 102(e)(1) date for the IA publication by WIPO is: None
 The § 102(e)(1) date for Publication by USPTO is: 01 May 2003
 The § 102(e)(2) date for the Patent is: 01 May 2003

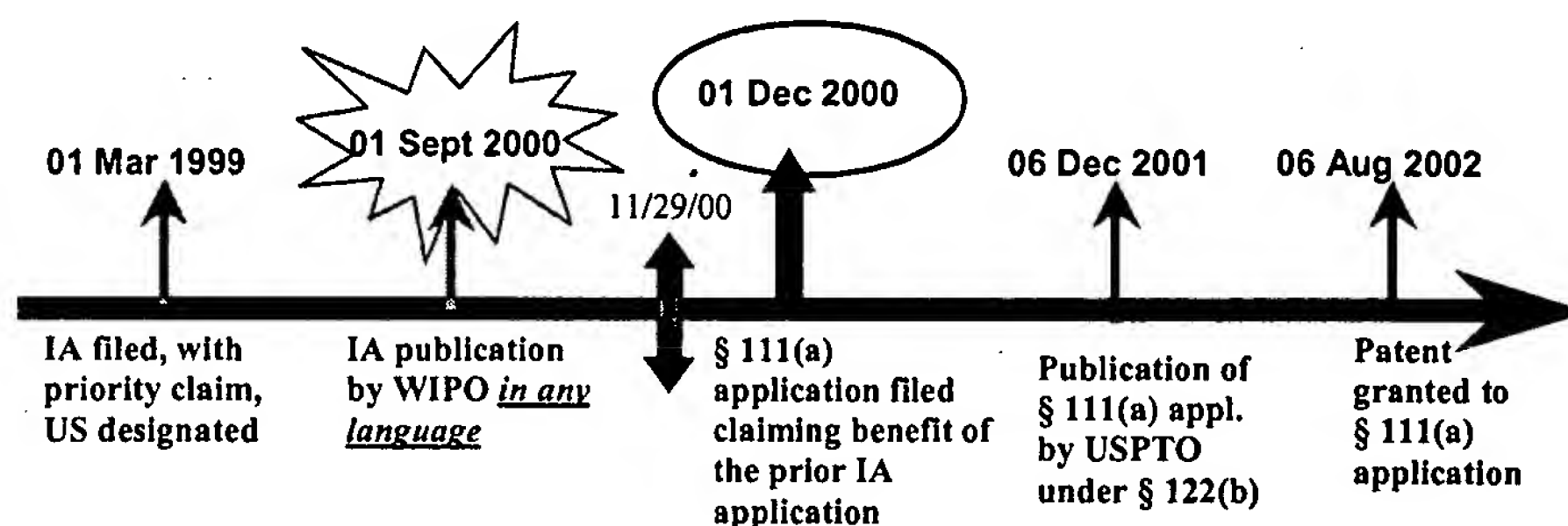
The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2002).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of the later-filed § 111(a) application in the example above (01 May 2003).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 May 2003).

Example 9: References based on a § 111(a) Application which is a **Continuation** (filed prior to any entry of the National Stage) of an **International Application**, which was **filed prior to November 29, 2000** (language of the publication under PCT Article 21(2) is not relevant)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation (filed prior to any entry of the National Stage) of an international application (IA) that was filed prior to November 29, 2000 have the § 102(e) prior art date of its actual U.S. filing date under § 111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) does not have a prior art date under § 102(e)(1) because the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.



The § 102(e)(1) date for the IA publication by WIPO is: None
 The § 102(e)(1) date for Publication by USPTO is: 01 Dec 2000
 The § 102(e) date for the Patent is: 01 Dec 2000

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2000).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of later-filed § 111(a) application in the example above (01 Dec 2000).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 Dec 2000).

FOR FURTHER INFORMATION CONTACT: Jeanne Clark or Robert Clarke, Legal Advisors in the Office of Patent Legal Administration, by telephone at (703) 305-1622, by fax at (703) 305-1013, or by e-mail addressed to Jeanne.Clark@USPTO.gov or Robert.Clarke@USPTO.gov.

12/11/02
[date]

/s/
Stephen G. Kunin
Deputy Commissioner
for Patent Examination Policy

¹ An original version of this Notice, signed on November 4, 2002, was posted on the Office's web site, and disseminated in paper copy form as a Pre-OG Notice as it was expected that the Notice would soon publish in the Official Gazette. In view of comments received, however, this revised version of the Notice additionally includes a clarification of Office policy in "(7) Final Rejection Practice" in Section IV of the Discussion portion, some further applicability notes in Examples 5 and 6 in Section V of the Discussion portion, and some minor edits. In addition, Item B of the Significant Provisions portion, the third paragraph of Section II of the Discussion portion and part (c)(ii) of "(4) Determine the appropriate § 102(e) date for each potential reference by following the guidelines below and examples set forth under Part V" in Section IV of the Discussion portion have been revised to note that the filing dates of international applications that designate the U.S. (which are filing dates in the U.S.) are only treated as prior art dates under 35 U.S.C. § 102(e) under certain circumstances. This revised Notice signed December 11, 2002, therefore, supercedes the original Notice.

² If the reference is a patent based on an International Application filed prior to November 29, 2000, § 102(e) prior to the AIPA is used to determine its § 102(e) prior art date.

³ The amendments to § 102(e) were set forth in section 4505 of the AIPA, as amended by H.R. 2215. The amendments to § 374 were set forth in section § 4507 of the AIPA, as amended by H.R. 2215.

⁴ The revision to 35 U.S.C. § 103(c) was made in § 4807 of the AIPA and is applicable only to applications filed on or after November 29, 1999.